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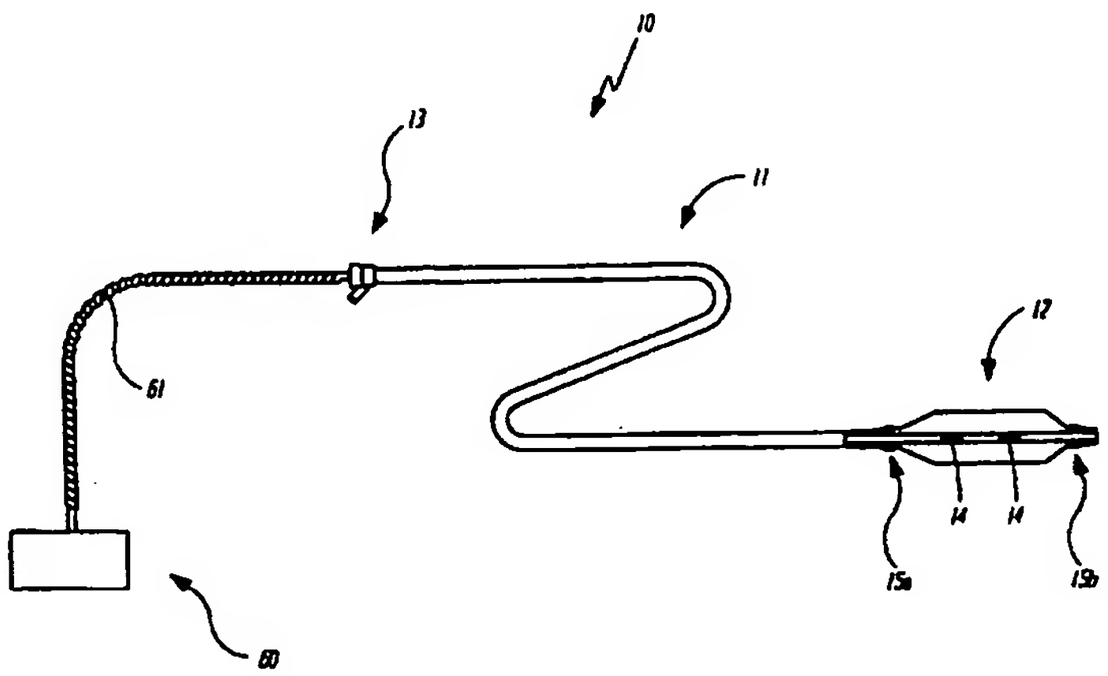

(57) Abstract

An apparatus and method for detecting a metallic stent inside a living body wherein the method includes the steps of: (1) providing a stent locator device, (2) providing a metallic stent, (3) inserting the metallic stent into the living body, (4) inserting the stent locator into the living body and (5) locating the stent with the sent locator by detecting an electrical parameter affected by the position of the stent relative to the position of the locating device. The electrical parameter may be detected with a pair of electrodes or a coil mounted to the distal end of the stent locator. The pair of electrodes may be made of electrically conductive ink which may be printed on an intraluminal device. The stent locator may include one or more radio-opaque markers mounted on the distal end such that the position of the stent may be radiographically correlated to the position of the stent locator device. Alternatively, the stent locator may include one or more visual markers mounted on the proximal end such that the position of the stent may be visually correlated to the position of the stent locator device. The stent locator may be in the form of virtually any intraluminal device such as a guide wire, a balloon catheter, an atherectomy catheter, a stent retrieval catheter, or a stent delivery catheter. In addition, the stent may be inserted prior to, subsequent to or simultaneously with the stent locator device.

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STENT LOCATING DEVICE

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation in part of U.S. Patent Application, Serial No. 08/612,158 filed on March 7, 1996 and entitled Stent Locating Device, the entire disclosure of which is hereby incorporated by reference.

Field of the Invention

The present invention generally relates to intraluminal devices used to locate metallic stents inside a living body. More specifically, the present invention relates to intravascular devices used to locate metallic stents inside the vasculature of a patient. Those skilled in the art will recognize the benefits of applying the present invention to similar fields not discussed herein.

Background of the Invention

Intravascular diseases are commonly treated by relatively non-invasive techniques such as percutaneous translumenal angioplasty (PTA) and percutaneous translumenal coronary angioplasty (PTCA). These therapeutic techniques are well known in the art and typically involve the use of a balloon catheter with a guide wire, possibly in combination with other intravascular devices. A typical balloon catheter has an elongate shaft with a balloon attached to its distal end and a manifold attached to the proximal end. In use, the balloon catheter is advanced over the guide wire such that the balloon is positioned adjacent a restriction in a diseased vessel. The balloon is then inflated and the restriction in the vessel is opened.

Vascular restrictions that have been dilated do not always remain open. The vessel may suddenly collapse shortly after dilation or the restriction may redevelop over a period of time. Acute closure (a.k.a. abrupt closure) refers to

the first situation where the vessel suddenly collapses shortly after dilation. Restenosis refers to the second situation where the restriction redevelops over a period of time. Various theories have been developed to explain the cause for these incidences. For example, it is commonly believed that acute closure occurs when the vascular restriction elastically recoils after dilation. It is also believed that abrupt closure may occur as a result of an intravascular dissection or tear caused by the dilation procedure. Restenosis, by contrast, is belived to be caused by cellular proliferation over a period of time to such a degree that a stenosis or restriction is reformed in the location of the previous dilation.

Intravascular stents are now commonly used as a means to prevent abrupt closure and as a means to reduce the effects of restenosis. An example of an intravascular stent is disclosed in U.S. Pat. No. 4,733,665 to Palmaz. Palmaz '665 discloses a metallic balloon expandable stent that is currently commercially available from Johnson & Johnson. The commercially available Palmaz stent is made of stainless steel and has a wall thickness on the order of 0.0025 inches for coronary applications and 0.004 inches for other applications. Given this wall thickness and material, the commercially-available Palmaz stent is relatively difficult to locate radiographically when the the stent is inside the patient. Accordingly, it is difficult to radiographically determine if a stent is properly positioned for deployment, if a stent has been deployed in the desired position or if the stent has changed position after deployment. Due to the difficulties in radiographic visualization, the dynamic properties of the heart and intravascular blood flow, the actual position of the stent may be significantly different from the desired position. Other commercially available stents have similar radiographic visualization difficulties.

Summary of the Invention

The present invention provides a device which allows the treating physician to easily determine the location of a metallic stent inside a patient, thus overcoming the disadvantages of the prior art. The present invention may be described as a method of detecting a metallic stent inside a living body wherein the method includes the steps of: (1) providing a stent locator device, (2) providing a metallic stent, (3) inserting the metallic stent into the living body, (4) inserting the stent locator into the living body and (5) locating the stent with the stent locator by detecting an electrical parameter affected by the position of the stent relative to the position of the locating device. The electrical parameter may be detected with a pair of electrodes or a coil mounted to the distal end of the stent locator. The pair of electrodes may be made of electrically conductive ink which may be printed on the stent locator device. If a pair of electrodes are used, the detected electrical parameter may be conductance. If a coil is used, the detected electrical parameter may be current. The stent locator may include a signal detector which is electrically-connected to either the electrodes or the coil mounted on the distal end of the stent locator device.

The stent locator may include one or more radiopaque markers mounted on the distal end such that the position of the stent may be radiographically correlated to the position of the stent locator device. Alternatively, the stent locator may include one or more visual markers mounted on the proximal end such that the position of the stent may be visually correlated to the position of the stent locator device.

The stent locator may be in the form of virtually any intraluminal device such as a guide wire, a balloon catheter, an atherectomy catheter, a stent retrieval catheter or a stent delivery catheter. In addition, the stent may be inserted prior to, subsequent to or simultaneously with the stent locator device.

The stent locator may also be used to determine the condition of the stent invivo. The stent locator may be used to determine among other things, whether a stent is properly mounted on a stent delivery or stent retrieval catheter, the degree to which a stent has been deployed, the location of the stent within the vasculature, the degree to which a stent has been embedded into the vasculature and the amount of vascular growth which may have covered a stent in the vasculature.

Brief Description of the Drawings

Figure 1a illustrates a partial plan view and a partial longitudinal cross-sectioned view of a stent locating device in the form of a balloon catheter. Figures 1b, 1c, and 1d show detailed sectioned views of the distal portion of the stent locating device illustrated in Figure 1a.

Figure 2a illustrates a partial plan view and a partial longitudinal cross-sectioned view of a stent locating device in the form of a guide wire. Figure 2b shows a detailed sectioned view of a portion of the stent locating device illustrated in Figure 2a.

Figure 3 illustrates a partial plan view and a partial longitudinal cross-sectioned view of an alternative stent locating device in the form of a balloon catheter.

Figure 4 illustrates a partial plan view and a partial longitudinal cross-sectioned view of a stent-locating device in the form of a stent delivery catheter.

Figure 5 illustrates a partial plan view and a partial longitudinal cross-sectioned view of a stent-locating device in the form of an atherectomy catheter.

Figure 6 illustrates a block diagram of suitable electronics for use in conjunction with the stent-locating device of the present invention.

Figure 7a illustrates a schematic diagram of suitable electronics for use in conjunction with the stent-locating device of the present invention.

Figure 7b illustrates an alternative schematic diagram of suitable electronics for use in conjunction with the stent-locating device of the present invention.

Figure 8 illustrates a partially cross-sectioned side view of an alternative stent-locating device.

Figure 9 illustrates a cross-section of the stent-locating device of Figure 8 taken along line A-A.

Figure 10 illustrates an alternative cross-section of the stent-locating device of Figure 8 taken along line A-A.

Figure 11 illustrates an end view of the distal end of the stent-locating device of Figure 8.

Figure 12 illustrates an expanded cross-section of the distal end of the stent-locating device illustrated in Figure 8.

Figure 13 illustrates a plan view of the distal end of an alternative stent-locating device.

Detailed Description of the Invention

The following detailed description should be read with reference to the drawings in which similar parts in different drawings are numbered identically. The drawings, which are not necessarily to scale, depict exemplary embodiments and are not intended to limit the scope of the invention.

Examples of materials, dimensions and manufacturing processes are provided for selected parts. All other parts employ that which is known to those skilled in the field of the invention. Those skilled in the art will recognize

that many of the examples provided have suitable alternatives which may also be utilized.

The stent locator device of the present invention may take the form of virtually any intraluminal device such as a guide wire, a balloon catheter, an atherectomy catheter or a stent delivery catheter. In addition, if the stent locating device is in the form of a catheter, the catheter may take the form of a single-operator-exchange (SOE), fixed wire (FW) or over-the-wire (OTW) type catheter and may be used in coronary, peripheral, cerebral and other vascular locations in addition to urethral, biliary and other non-vascular locations. Other features such as perfusion and drug delivery may also be incorporated into the stent locating device. For the purpose of the following discussion, the exemplary embodiments are directed to a catheter system which is particularly suitable for PTCA procedures. However, with simple modifications in construction, the stent-locating device of the present invention may be used for other medical applications not fully discussed herein.

Refer now to Figure 1a which illustrates a plan view of a stent locating device 10 in the form of a balloon catheter. The stent locating device 10 includes an elongate shaft 11 with a balloon 12 connected to its distal end and a manifold assembly 13 connected to its proximal end. The manifold assembly 13 facilitates connection to an inflation device (not shown) and stent locating circuitry 60 via flexible cord 61. Manifold assembly 13 may also include additional ports for other purposes such as insertion of a guide wire, connection to infusion system, etc. Stent locating device 10 may also include a pair of radio-opaque marker bands 14 connected to the portion of the shaft 11 that traverses the interior of the balloon 12. Except as discussed hereinafter, stent locating device 10 may be manufactured in a conventional manner. For example, stent locating device 10 may be manufactured as described in U.S.

Patent No. 5,338,295 to Cornelius et al., U.S. Patent No. 5,370,616 to Keith et al., U.S. Patent No. 5,382,234 to Cornelius et al., or U.S. Patent No. 5,387,225 to Euteneuer et al.

Stent locating device 10 also includes two pairs of electrodes 15a and 15b mounted on the proximal and distal waists, respectively, of the balloon 12. As best illustrated in Figure 1b, a pair of insulated electrical leads 16a are connected to proximal electrode pair 15a. In a similar manner, a pair of insulated electrical leads 16b are connected to distal electrode pair 15b. In this particular embodiment which illustrates a coaxial OTW catheter construction, both pairs of insulated electrical leads 16a and 16b extend to the manifold assembly 13 through the elongate shaft 11 by way of the annular inflation lumen defined between inner tube 17 and outer tube 18. The proximal pair of insulated electrical leads 16a gains access to the annular inflation lumen by wrapping around the proximal edge of the proximal waist of the balloon through the adhesive bond between the outer tube 18 and the proximal waist of the balloon 12 and around the distal edge of the outer tube 18. In a similar manner, the distal pair of insulated electrical leads 16b gains access to the annular inflation lumen by winding around the distal edge of the distal waist of the balloon 12 and passing through the adhesive bond between the distal end of the inner tube 17 and the distal waist of the balloon 12.

As best seen in Figures 1c and 1d, proximal and distal electrode pairs 15a and 15b include two discrete electrodes each. In particular, proximal electrode pair 15a includes a proximal electrode 15a(1) and a distal electrode 15a(2). In a similar manner, distal electrode 15b includes a proximal electrode 15b(1) and a distal electrode 15b(2). Each discrete electrode 15a(1), 15a(2) and 15b(1), 15b(2) is separated by an insulated spacer 19a, 19b. An adhesive coating is applied to each electrode pair 15a and 15b to secure the electrode to the balloon 12 and to

provide an insulating barrier. The adhesive barrier prevents direct contact between the electrodes and the interior of the vasculature. A portion of the adhesive coating is removed such that the proximal facing portion of the proximal electrodes 15a(1), 15b(1) and the distal facing portions of the distal electrodes 15a(2), 15b(2) are exposed.

As an alternative, it is contemplated that the electrodes may have an outer surface that is exposed to enable direct contact with the vessel wall. In this embodiment, the electrodes may be used to detect the degree of stent deployment. For example, a stent that is imbedded in tissue will have a different reading than a stent that is not imbedded, due to the different electrical characteristics of metallic stents, bodily fluids and bodily tissues.

With this arrangement of electrodes, an electrical path is defined by proximal electrode 15a(1) through its immediate exterior environment to distal electrode 15a(2). In a similar manner, an electrical path is defined between proximal electrode 15b(1) through its immediate exterior environment to distal electrode 15b(2). Each of these electrical paths are separately communicated to the stent locating circuitry 60 by way of insulated electrical leads 16a, 16b and flexible cord 61. As will be discussed in more detail hereinafter, the portion of the electrical path defined by the environment immediately adjacent the electrode pairs 15a, 15b is influenced by the presence of different materials such as blood, bodily tissue and foreign materials such as intralumenal stent. Accordingly, as each electrode pair 15a and 15b passes through an electrical environment that changes, the electrical path defined by that environment will also change.. The change in electrical path may be detected by stent locating circuitry 60.

Electrodes 15a(1), 15a(2) and 15b(1), 15b(2), in addition to insulated electrical leads 16a and 16b may be made of 42AWG HML silver wire which

includes an insulating coating of polyimide. For biocompatability and anti-corrosion purposes, it may be preferable to use nickle-plated silver, platinum-plated silver or solid platinum. Solid platinum and platinum-plated silver may have the advantage of being more radio-opaque than other suitable metallic materials. Each electrode may be wound around the balloon waist once and spaced apart by insulating spacers 19a and 19b. Insulating spacers 19a, 19b may be formed of a suitable biocompatible insulating material such as polyethylene or polytetrafluoroethylene (PTFE) having a wall thickness approximating the diameter of the wire and having a length of about 0.050 inches. The electrode pairs 15a and 15b may be adhesively secured to the balloon waists by a suitable insulating adhesive such as a UV-curable urethane adhesive.

Proximal electrode pair 15a is spaced apart from distal electrode pair 15b by approximately 2 - 4 millimeters less than the length of the stent to be detected. For example, if a 15-mm length stent is to be detected, the proximal electrode pair 15a may be spaced 11 to 13 mm from the distal electrode pair 15b. This arrangement permits both electrode pairs 15a and 15b to be within the length of the stent which in turn facilitates precise determination of the position of the stent.

Although a two-pair electrode system is described above, it is contemplated that a single electrode pair may also be utilized. For example, either the proximal electrode pair 15a or the distal electrode pair 15b may be used to the exclusion of the other. Having a single electrode pair mounted on the proximal end of the balloon has the advantage of not increasing catheter profile at the distal end of the catheter (which may impede the ability of the catheter to cross tight restrictions), but has the disadvantage of requiring the balloon to be advanced distally of the stent in order to determine the precise

position of the stent. Utilizing a single electrode pair mounted on the distal end of the balloon has the advantage of not requiring the balloon to be advanced distally of the stent in order to determine the position of the stent, but has the disadvantage of increasing the profile of the catheter at its distal end which may impede the ability of the catheter to cross tight restrictions.

It is also contemplated that a single electrode pair may be utilized wherein the proximal electrode is mounted to the proximal waist of the balloon and the distal electrode is mounted to the distal waist of the balloon. It is believed that having an electrode pair with the proximal electrode immediately adjacent the distal electrode (e.g., 15a(1) and 15a(2)) reduces the effects of varying anatomical geometries which may adversely influence the detected electrical path.

The stent locating device 10 may be used, for example, to detect the position of a previously-inserted stent or to aid in the insertion of a stent. Accordingly, the stent locating device 10 may be inserted prior to, subsequent to, or simultaneously with a stent. For purposes of the following discussion, assume that a stent has been previously inserted into the coronary vasculature.

With the stent positioned in vivo, the stent locating device 10 may be inserted into the proper vascular path by conventional methods using conventional devices such as a guide catheter and/or a guide wire. With the stent locating device 10 positioned in vivo, a base reading is taken and the stent locating circuitry 60 is adjusted such that the signal meter 68 is calibrated to indicate a nominal inside diameter with no stent present. Once the stent locating circuitry 60 is calibrated, the stent locating device 10 is advanced until a signal is indicated on the signal meter 68. This first signal represents the distal electrode pair 15b crossing the proximal edge of the previously-inserted stent. The stent locating device 10 is then advanced until a second signal is

indicated on the signal meter which represents the proximal electrode pair 15a crossing the proximal edge of the previously-inserted stent. The stent locating device 10 is then advanced slightly further until the signal from the distal electrode pair 15b drops off indicating that the distal electrode pair 15b has crossed the distal edge of the stent. At this point, the stent locating device 10 may be retracted in the proximal direction until the signal from the proximal electrode pair 15a drops off, indicating that the proximal electrode pair 15a has re-crossed the proximal edge of the stent. This iterative process is repeated until the position of the proximal and distal edges of the stent are apparent. Accordingly, the position of the previously-inserted stent is directly related to the position of the stent locating device 10. After completion of the procedure, the stent locating device 10 may be removed from the patient.

The position of the stent relative to the anatomy may be correlated by determining the position of the stent locating device 10 relative to the anatomy. The position of the stent locating device 10 relative to the anatomy may be determined by at least two different methods. For example, the position of the stent locating device 10 may be determined radiographically utilizing the radiopaque marker bands 14 mounted on the distal end of the elongate shaft 11. Since the anatomy and the radiopaque marker bands 14 are radiographically visible by conventional methods, the position of the stent is directly correlated to the position of the marker bands 14.

An alternative method utilizes visual marks (not shown) on the proximal end of the elongate shaft 11. These visual marks may be positioned at known distances from the proximal and distal electrode pairs 15a, 15b. The position of the visual marks may be compared to another previously-inserted radiographically-visible device such as a guide catheter and/or a guide wire with a known length. For example, a visual mark may be placed on the

elongate shaft 11 at a distance of 110 cm from the center of the electrode pairs 15a, 15b. With this visual mark positioned adjacent the proximal end of a 100 cm guide catheter, the electrode pairs must be centered 10 cm from the distal end of the guide catheter. A plurality of visual marks may be spaced along the proximal end of the elongate shaft 11 at known incremental distances to facilitate precise determination of the position of the electrode pairs 15a and 15b.

As mentioned previously, the stent locator of the present invention may be in the form of a guide wire such as the guide wire 20 illustrated in Figures 2a and 2b. Stent locating guide wire 20 includes an elongate shaft 21 with an atraumatic tip 22 mounted to its distal end and a manifold assembly 23 connected to its proximal end. Atraumatic tip 22 may, for example, be in the form of a spring tip which is well-known in the art. Shaft 21 includes a core 24 manufactured by conventional methods and an outer sheath 25 disposed thereon. The outer sheath 25 has a distal end which abuts the proximal end of the atraumatic tip 22. Preferably, the outer diameter of the outer sheath 25 approximates the outer diameter of the atraumatic tip 22 to provide a smooth transition therebetween.

Outer sheath 25 includes a single pair of electrodes 26a and 26b, but may also include two or more pairs. Proximal and distal electrodes 26a and 26b electrically communicate with the stent locating circuitry 60 by way of insulated electrical leads 27a, 27b and flexible cord 61. An insulating barrier such as a polymer coating may be applied to the proximal and distal electrodes 26a and 26b to avoid direct contact with the inside of the vasculature. The proximal and distal edges of the electrodes 26a and 26b remain exposed to maintain an electrical path with the surrounding environment.

Outer sheath 25 may be made of polyimide by conventional methods. Proximal and distal electrodes 26a and 26b may be made by plating a conductive metal such as silver or gold onto the exterior of the sheath 25 and etching away the unneeded portions of the coating. Alternatively, the outer sheath 25 may masked or screened such that a metallic coating is applied only in the desired locations. The proximal electrode 26a may be formed in a semi-circular geometry to allow passage of the distal electrical lead 27b. Electrical leads 27a and 27b may be formed in the same manner as the proximal and distal electrodes 26a and 26b.

The stent locating device 20 may be used in substantially the same way as the stent locating device 10. Note, however, that the stent locating device 20 shows only a single pair of electrodes whereas the stent locating device 10 shows two pairs of electrodes. As mentioned previously, the number and arrangement of electrodes may vary, depending on the competing factors considered to be most desirable.

Refer now to Figure 4 which illustrates an alternative electrode system. Stent locating device 30 is made and used the same as stent locating device 10 with the following exceptions. Stent locating device 30 includes a coil 36 wound about the inner tube 17 under the balloon 12. Marker bands 14 are positioned equi-distant either side of the coil 36. The coil 36 is electrically connected to stent locating circuitry 60 by way of insulated electrical leads 37a, 37b and flexible cable 61.

The principles of operation of stent locating device 30 differ from the principles discussed with reference to stent locating device 10 in that a stent is located by detecting changes in an electrical field surrounding the coil 36. The principles of operation of stent locating device 10 are based in part on changes in electrical paths versus stent locating device 30 which are based in part on

changes in electrical fields. In particular, as a metallic object moves past coil 36, an electromotive force is generated which may be detected by suitable circuitry. Although only one coil is illustrated on the stent locating device 30, two or more coils may be utilized depending on the competing factors found most desirable.

Preferably, coil 36 is made of about to 100 to 500 turns of AWG 50 insulated wire such as silver, copper or platinum having a length of about 0.1 to 0.5 inches. One or more coils may be used and the either a single layer or multiple layers may be utilized.

It is contemplated that a single coil may be used in combination with an external electrode connected to the patient. In this embodiment, the capacitance will change as a function of the presence or absence of a stent.

It is further contemplated that a single coil may be used in combination with an external antenna with a radio transmitter connected to the coil (internal antenna) and a receiver connected to the external antenna. In this embodiment, the electromagnetic signal will change as a function of the presence or absence of a stent which interferes with radio waves.

Refer now to Figure 4 which illustrates a stent locating device 40 in the form of a stent delivery device. The stent delivery device is manufactured and used in the same way as stent locating device 10 with the following exceptions. Stent locating device 40 includes a stent 41 mounted on the balloon 12 (shown in the expanded state). Stent locating device 40 also includes a retractable sheath 42 (shown in a retracted position) which secures the stent 41 to the balloon 12 until the stent 41 is ready for deployment. An example of a similar stent delivery system (with exception of the stent locating features) is disclosed in U.S. Patent No. 5,092,877 to Pinchuk.

Refer now to Figure 5 which shows a stent locating device 50 in the form of an atherectomy catheter. Stent locating device 50 includes a rotational cutter 52 mounted on the distal end of a drive shaft 51. Rotational cutter 52 may include an abrasive coating 53 to facilitate differential cutting of intravascular tissue. Drive shaft 51 is hollow such that a guide wire 20 may be inserted therein. Guide wire 20 may be substantially as described with reference to Figures 2a and 2b. An example of a similar atherectomy device (with exception of the stent locating features) is disclosed in U.S. Patent No. 4,445,509 to Auth.

Refer now to Figure 6 which illustrates a block diagram of the stent locating circuitry 60 as used with a single pair of electrodes. If more than one pair of electrodes are used, an additional stent locating circuit may be used or a switch may be provided to alternate between pairs of electrodes. The stent locating circuitry includes a flexible cord 61 which is electrically connected to a pair of electrodes designated electrode # 1 and electrode # 2.

The electrical environment 80 in which the electrodes are used is schematically represented as a parallel RC circuit wherein R_S is the resistance of the stent, R_t is the resistance of the surrounding tissue and C_t is the capacitance of the surrounding tissue.

Stent locating circuitry 60 includes a signal generator 62 which generates an AC signal on the order of 0.1 to 10 MHz. Signal generator 62 is connected to an amplifier 63 which includes a current limiter. Amp 63 is connected to a DC blocker 64 which prevents DC current from passing through to the electrodes (in order to avoid inducement of adverse cardiac currents). The DC blocker 64 is connected to a first electrode via flexible cord 61. The opposite electrode is also connected to flexible cord 61, which in turn is connected to amp 65 which includes a current-to-voltage converter. Amp 65 is connected to band pass filter 66 which freely passes currents having specified frequencies and highly

attenuates currents with frequencies outside the nominal limits. Band pass filter 66 is connected to an AC-to-DC converter 67, which in turn is connected to a signal meter 68. Signal meter 68 preferably includes a series of LED's having three different colors. For example, green may be used to indicate a base line signal which corresponds to the nominal inside diameter of the intralumenal path. Yellow may be used to indicate a damped signal which corresponds to a vascular restriction. The damped signal occurs in a vascular restriction because blood is generally more conductive than abnormal deposits. A damped signal may also indicate a gap within a stent such as an articulated stent. Red may be used to indicate a peak signal, representing a fully-expanded stent. The peak signal occurs in an expanded stent because a stent is generally more conductive than both blood and abnormal deposits.

Figure 7a illustrates a schematic diagram of a particularly suitable circuit for use in combination with the stent locating device of the present invention. Figure 7b illustrates an alternative schematic diagram of suitable electronics for use in conjunction with the stent-locating device of the present invention.

Figure 8 depicts an alternative embodiment of the stent locating device where a catheter 110 may have a display 115 attached to its proximal end. Catheter 110 may be a balloon catheter as previously described except as described hereinafter. The features of the alternative stent locating device shown in Figure 8 may also be incorporated into the stent locating devices as described previously.

Display 115 may be permanently bonded to catheter 110 and may be molded such that it will comfortably fit into the hand of the user. Mounted on display 115 may be two rows of lights where each row may have five lights. Distal indicating lights 117 may be located closer to the distal end of display 115 and proximal indicating lights 118 may be located closer to the proximal end of

display 115. Display 115 may also have an on switch 124 and an off switch 119 which may turn the display on and off. Display 115 further may have an inflation port 120 which may be attached to an inflation device. Display 115 may also have a guide wire port 122 suitable for providing access for a guide wire.

A cross section of body section 130 taken along lines A-A is depicted in Figure 9 where a typical dual lumen catheter design has been modified to accommodate a third lumen 137 for electrical leads 140 and 141. Body section 130 may have a main shaft 133, an inflation lumen 135, a guide wire tube 139 and a lumen 137 for leads 140 and 141. Leads 140 and 141 may be bi-filar silver wires coated with an insulation where the total outside diameter may be about .001-.005 inches and preferably about .0045 inches. Suppliers of suitable wire for leads include California Wire Products Corporation of Corona, CA or Phelps Dodge Corporation of Phoenix, AZ. Guide wire tube 139 may be connected to the guide wire port 122 and inflation lumen 135 may be connected to inflation port 120. Leads 141 and 140 may be connected to the circuitry shown in Figure 7a or 7b and contained within display 115.

An alternative embodiment of body section 130 is shown in Figure 10 where leads 140 and 141 may be located within inflation lumen 135. This embodiment may use the coating on leads 140 and 141 to protect the metal leads 140 and 141 from contacting inflation fluid. This embodiment may make it possible to make catheter 110 with a smaller diameter since no lead lumen is provided. In another embodiment leads 140 and 141 may be made by printing a conductive ink on inner tube 139. Preferable conductive inks are discussed in greater detail below.

Referring again to Figure 8, balloon 150 may be bonded to the distal end of shaft 133. Guide wire tube 139 continues distally under balloon 150 until the

distal end of guide wire tube 139 may be bonded to the distal waist of balloon 150. At least one radio-opaque marker band may be attached to guide wire tube 139 and in a preferred embodiment two marker bands 152 and 153 may be swaged around the guide wire tube 139 beneath balloon 150. Lead lumen 137 also continues distally under balloon 150 and terminates near the distal waist of balloon 150. Leads 140 and 141 exit lead tube 139 near the proximal balloon waist.

Leads 141 split into single strands which may connect with electrode pair 155. Electrode pair 155 is depicted in an end view of catheter 110 shown in Figure 11. Figure 12 shows an expanded cross section of the distal waist of balloon 150. Electrode pair 155 may be made by printing conductive ink on the distal waist of balloon 150. A variety of conductive adhesives or inks may be used including solid silver, solid gold, silver/silver chloride, stainless steel, and silver/gold where a suitable supplier of conductive inks may be Creative Materials, Inc. located in Tyngsboro, MA. The conductive ink may be applied by a variety of methods including sputter coating, vapor deposition, plating, or printing. Further printing methods include stamping or airbrushing, and preferably the ink is applied by pad printing. The electrodes may be printed on an uninflated balloon in any suitable pattern including a triangular shape as shown in Figure 11.

In another embodiment the electrodes may consists of several layers of conductive ink. Several layers may be used to enhance certain properties or add multiple individual properties. For instance, gold based inks are more radio-opaque than other inks but may not be the best electrode material. Mulitiple layers of gold combined with layers of another type of ink may produce an electrode that is both radio-opaque and have other advantageous properties. Further, several layers of ink may be used to replace the marker

bands. Additional marker bands may then be printed on the catheter 110 or the electrodes may be radio-opaque enough that marker bands are unnecessary for fluoroscopic viewing.

Assembly of the lead to electrode connections may be best understood by reference to Figure 12. Half of electrode pair 155 may be printed on the waist of balloon 150. Since the electrode pairs 155 are printed on uninflated balloons, a small portion 160 of the inflated balloon waist may not be covered. Typically this portion 160 is about .5 mm for a balloon that is 13 mm long.

A hole 161 may then be drilled through the electrode 155 and the balloon waist. Lead 141 may then be placed into the hole as shown in Figure 12. A conductive urethane ink or epoxy 163 may be used to fill in the hole, bond the lead 141 to the electrode 155, and establish a conductive path between the lead 141 and the electrode 155. A suitable conductive epoxy may be Ellsworth 402 made by the Resin Technology Group in Easton, MA. An insulating coating 164 may then be coated over most of the electrode 155 including the hole 161. Suitable insulating coating include urethane coatings. A contact portion 166 of the electrode may be left uninsulated. The contact 166 is the point where electrode 156 electrically interacts with objects external to catheter 110. Finally, the distal tip of catheter 110 may be formed by a urethane back-filling material 168 onto the end of catheter 110. A suitable urethane may be 3507 from BF Goodrich. Similarly electrode pair 157 may be printed onto the proximal waist of balloon 150 and connected to electrode 140.

Referring to Figure 13 an alternative electrode pattern is shown on balloon 150. This pattern shows a first electrode 172 located near the proximal end of balloon 150, an array of electrodes 171 spaced about the balloon 150, and a last electrode 170 located near the distal end of balloon 150. Electrodes 170 and 172 may be connected to leads as described above, while the intermediate

leads may be electrically isolated. When any of the electrodes come into contact with a stent the resistance of a circuit including lead 170 and 172 will decrease. Accordingly, the more electrodes that come into contact with the stent the lower the resistance. This resistance may then be used to determine some conditions of a stent including whether the stent remains properly mounted on a balloon during delivery, whether the stent has been firmly captured by a stent retrieval device, the degree of deployment once the stent has been delivered to a treatment site, the degree to which a stent has been overgrown by the vascular wall, or the longitudinal growth of the balloon relative to a stent.

Referring back to Figure 8, display 115 may be connected via leads 140 and 141 to electrode pairs 155 and 157. Distal indicating lights 117 indicate the proximity of electrode pair 155 to a metal object. The number of lights that light correspond to the strength of a signal coming from the electrode pair 155. The closer the electrode pair 155 is to the stent the stronger the signal. A peak signal will be displayed on distal indicating light 117 by as many as five lights being lit. Similarly proximal indicating lights also indicate the proximity of electrode pair 157 to a metallic object.

Similar techniques may be used to print electrode pairs onto a variety of intravascular devices including stent retrieval catheters, guide wires, balloon catheters, atherectomy catheters, and stent delivery catheters

In use, catheter 110 may be inserted into the vasculature and advanced over a guide wire to a position near a stent that is to be located. As electrode pair 155 comes close to the proximal end of the stent, distal display 117 will vary from no signal to full signal depending on the proximity of the electrode pair 155 to the stent. The strength of full signal will depend on how much growth may have covered the stent where, in the case of a freshly placed stent, full signal may be all five lights lit on distal display 117. Because of the high

sensitivity of the stent finder, variations in the growth over the stent, the amount that the stent is embedded into the vessel wall, and even gaps such as articulations in the stent will create a signal that is less than peak. Catheter 110 may then be further advanced until no signal is present. The catheter may be moved back and forth until the distal edge of the stent is clearly determined.

Similarly, the proximal electrode pair 157 will move from no signal to peak signal as the electrode is moved into the stent. It may therefore be necessary to move the stent finder through the stent several times to determine where both the proximal and distal edges of the stent are. Once the edges of the stent have been determined, marker bands 152 and 153 will indicate the position of the stent under fluoroscopy or visual markers on the shaft will indicate the position of the stent visually. Once the stent location is determined, highly accurate post-delivery dilatation of the stent may be done. Balloon 150 may be about 13 mm in length to best fit commercially available stents. It may further be appreciated by those skilled in the art that different sized balloons may be appropriate depending on the size of the stent.

While the specification describes the preferred embodiments, those skilled in the art will appreciate the scope and spirit of the invention with reference to the appended claims.

I claim:

1. An apparatus for determining the condition of a stent invivo comprising:

an elongate member having a proximal end and a distal end;

at least one pair of electrodes mounted on the distal end of the elongate member;

an electrically conductive path extending from the distal end of the elongate member to the proximal end of the elongate member and in electrical connection with the at least one pair of electrodes; and

a display connected to the electrically conductive path near the proximal end of the elongate member and configured to display the condition of the stent invivo.

2. The apparatus for determining the condition of a stent of claim 1 wherein the elongate member is a medical device selected from the group consisting of stent retrieval catheters, guide wires, balloon catheters, atherectomy catheters, and stent delivery catheters.
3. The apparatus for determining the condition of a stent of claim 1 wherein the at least one pair of electrodes are printed on the distal end of the elongate member.
4. The apparatus for determining the condition of a stent of claim 1 wherein the at least one pair of electrodes are made of an electrically conductive ink.
5. The apparatus for determining the condition of a stent of claim 1 wherein the electrically conductive path is made of a conductive ink.
6. The apparatus for determining the condition of a stent of claim 1 wherein the display comprises a system of lights configured to depict the condition of the stent.

7. The apparatus for determining the condition of a stent of claim 1 wherein the condition is a position of the stent.

8. The apparatus for determining the condition of a stent of claim 1 wherein the condition is a degree of deployment of the stent.

9. The apparatus for determining the condition of a stent of claim 1 wherein the condition is a degree to which the stent is embedded in tissue surrounding a body lumen.

10. The apparatus for determining the condition of a stent of claim 1 wherein the condition is a degree to which vascular tissue has covered the stent.

11. The apparatus for determining the condition of a stent of claim 1 wherein the electrodes are used to measure a parameter of the stent.

12. A method of determining the condition of a stent while the stent is in a human body lumen, the method comprising:

providing an elongate member having a proximal end, a distal end, at least one electrically conductive path therethrough, at least one pair of electrodes mounted on the distal end of the elongate member and in electrical connection with the at least one electrically conductive path, and a display in electrical connection with the at least one electrically conductive path;

advancing the elongate member through the body lumen until it is adjacent the stent;

sensing the condition of the stent; and

depicting the condition of the stent on the display.

13. The method of determining the condition of a stent of claim 12 wherein the elongate member is a medical device selected from the group consisting of

stent retrieval catheters, guide wires, balloon catheters, atherectomy catheters, and stent delivery catheters.

14. The method of determining the condition of a stent of claim 12 wherein the condition of the stent is the position of the stent within the lumen.

15. The method of determining the condition of a stent of claim 12 wherein the condition of the stent is the degree of deployment of the stent.

16. The method of determining the condition of a stent of claim 12 wherein the condition of the stent is the degree to which the stent is embedded in tissue surrounding the lumen.

17. The method of determining the condition of a stent of claim 12 wherein the condition of the stent is the degree that the stent is covered by vascular tissue.

18. The method of determining the condition of a stent of claim 12 wherein the condition of a stent is sensed by measuring an electrical parameter.

19. The method of determining the condition of a stent of claim 12 wherein the elongate member includes at least one radio-opaque marker mounted on the elongate member a known distance from the at least one pair of electrodes.

20. The method of determining the condition of a stent of claim 19, further comprising the step of:

radiographically locating the radio-opaque marker on the elongate member to determine the position of the stent.

21. The method of determining the condition of a stent of claim 12 wherein the at least one radio-opaque marker is printed on the elongate member.

22. The method of determining the condition of a stent of claim 12 wherein the elongate member includes at least one visual marker mounted near the proximal end.

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23. The method of determining the condition of a stent of claim 22, further comprising the step of:

visually locating the visual marker on the elongate member to determine the position of the stent.

24. A method of detecting a metallic stent inside a living body, comprising the steps of:

(i) providing a stent locator device having a proximal end, a distal end and a pair of electrodes mounted on the distal end;

(ii) providing a metallic stent;

(iii) inserting the metallic stent inside the living body;

(iv) inserting the stent locator inside the living body; and

(v) locating the stent with the stent locator by detecting an electrical parameter when the electrodes on the stent locator are positioned adjacent the stent.

25. A method of detecting a metallic stent inside a living body as in claim 24, wherein the stent locator includes a signal detector electrically connected to the electrodes.

26. A method of detecting a metallic stent inside a living body as in claim 25, wherein the detected electrical parameter is conduction.

27. A method of detecting a metallic stent inside a living body as in claim 26, wherein the stent locator device includes at least one radiopaque marker mounted on the distal end.

28. A method of detecting a metallic stent inside a living body as in claim 27, further comprising the step of:

(vi) radiographically locating the radiopaque marker on the stent locator to determine the position of the stent.

29. A method of detecting a metallic stent inside a living body as in claim 26, wherein the stent locator device includes at least one visual marker mounted on the proximal end.

30. A method of detecting a metallic stent inside a living body as in claim 29, further comprising the step of:

(vi) visually locating the visual marker on the stent locator to determine the position of the stent.

31. A method of detecting a metallic stent inside a living body as in claim 26, wherein the stent locator is a guide wire.

32. A method of detecting a metallic stent inside a living body as in claim 26, wherein the stent locator is a balloon catheter.

33. A method of detecting a metallic stent inside a living body as in claim 26, wherein the stent locator is an atherectomy catheter.

34. A method of detecting a metallic stent inside a living body as in claim 26, wherein the stent locator is a stent delivery catheter.

35. A method of detecting a metallic stent inside a living body as in claim 26, wherein the stent is inserted prior to the stent locator.

36. A method of detecting a metallic stent inside a living body as in claim 26, wherein the stent locator is inserted prior to the stent.

37. A method of detecting a metallic stent inside a living body as in claim 26, wherein the stent and the stent locator are inserted simultaneously.

38. A method of detecting a metallic stent inside a living body, comprising the steps of:

(i) providing a stent locator device having a proximal end, a distal end and a coil mounted on the distal end;

(ii) providing a metallic stent;

(iii) inserting the metallic stent inside the living body;

(iv) inserting the stent locator inside the living body; and

(v) locating the stent with the stent locator by detecting an electrical parameter when the electrodes on the stent locator are positioned adjacent the stent.

39. A method of detecting a metallic stent inside a living body as in claim 38, wherein the stent locator includes a signal detector electrically connected to the coil.

40. A method of detecting a metallic stent inside a living body as in claim 39, wherein the detected electrical parameter is current.

41. A method of detecting a metallic stent inside a living body as in claim 38, wherein the stent locator device includes at least one radiopaque marker mounted on the distal end.

42. A method of detecting a metallic stent inside a living body as in claim 40, further comprising the step of:

(vi) radiographically locating the radiopaque marker on the stent locator to determine the position of the stent.

43. A method of detecting a metallic stent inside a living body as in claim 39, wherein the stent locator device includes at least one visual marker mounted on the proximal end.

44. A method of detecting a metallic stent inside a living body as in claim 38, further comprising the step of:

(vi) visually locating the visual marker on the stent locator to determine the position of the stent.

45. A method of detecting a metallic stent inside a living body as in claim 39, wherein the stent locator is a guide wire.

46. A method of detecting a metallic stent inside a living body as in claim 39, wherein the stent locator is a balloon catheter.

47. A method of detecting a metallic stent inside a living body as in claim 39, wherein the stent locator is an atherectomy catheter.

48. A method of detecting a metallic stent inside a living body as in claim 39, wherein the stent locator is a stent delivery catheter.

49. A method of detecting a metallic stent inside a living body as in claim 39, wherein the stent is inserted prior to the stent locator.

50. A method of detecting a metallic stent inside a living body as in claim 39, wherein the stent locator is inserted prior to the stent.

51. A method of detecting a metallic stent inside a living body as in claim 39, wherein the stent and the stent locator are inserted simultaneously.

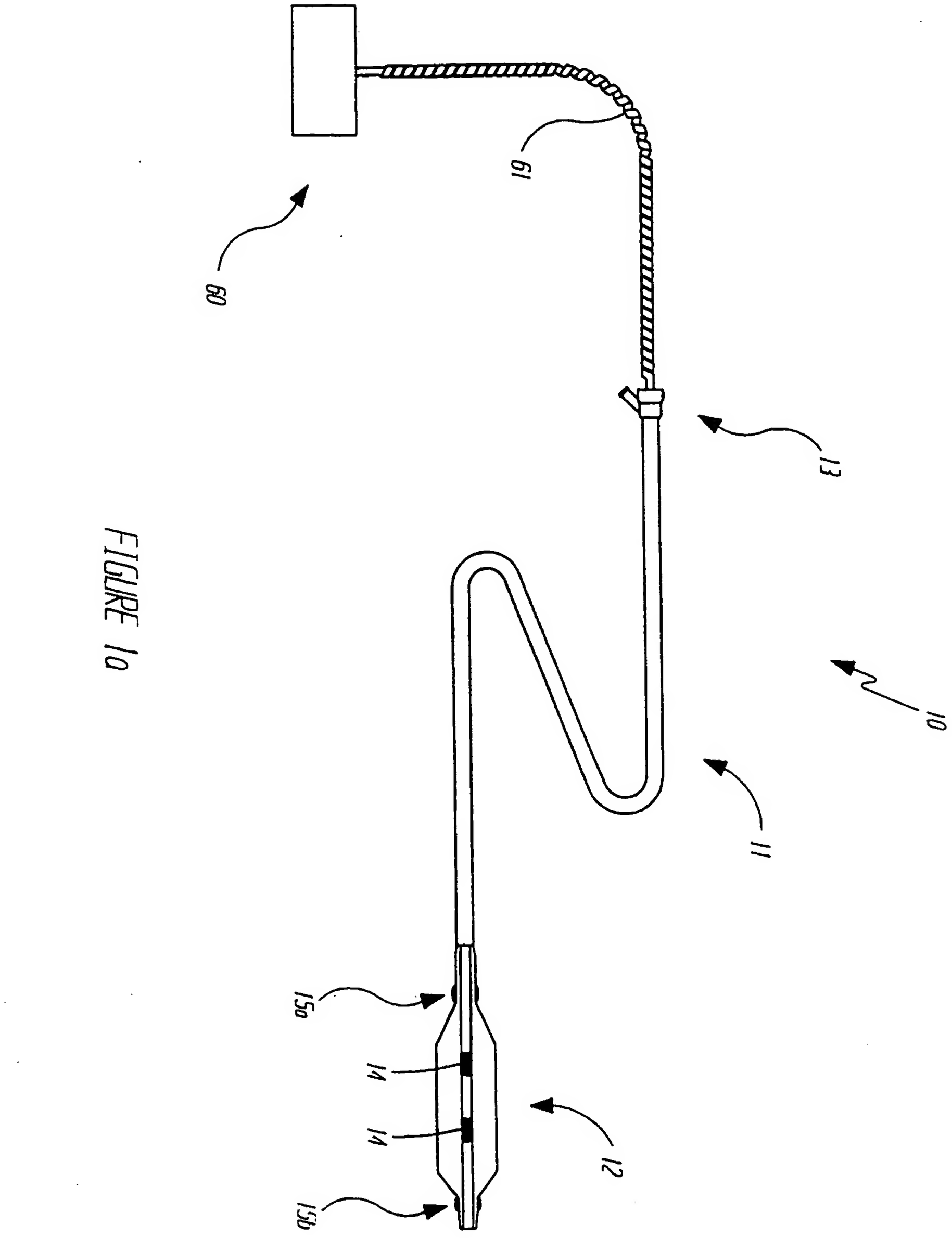


FIGURE 1o

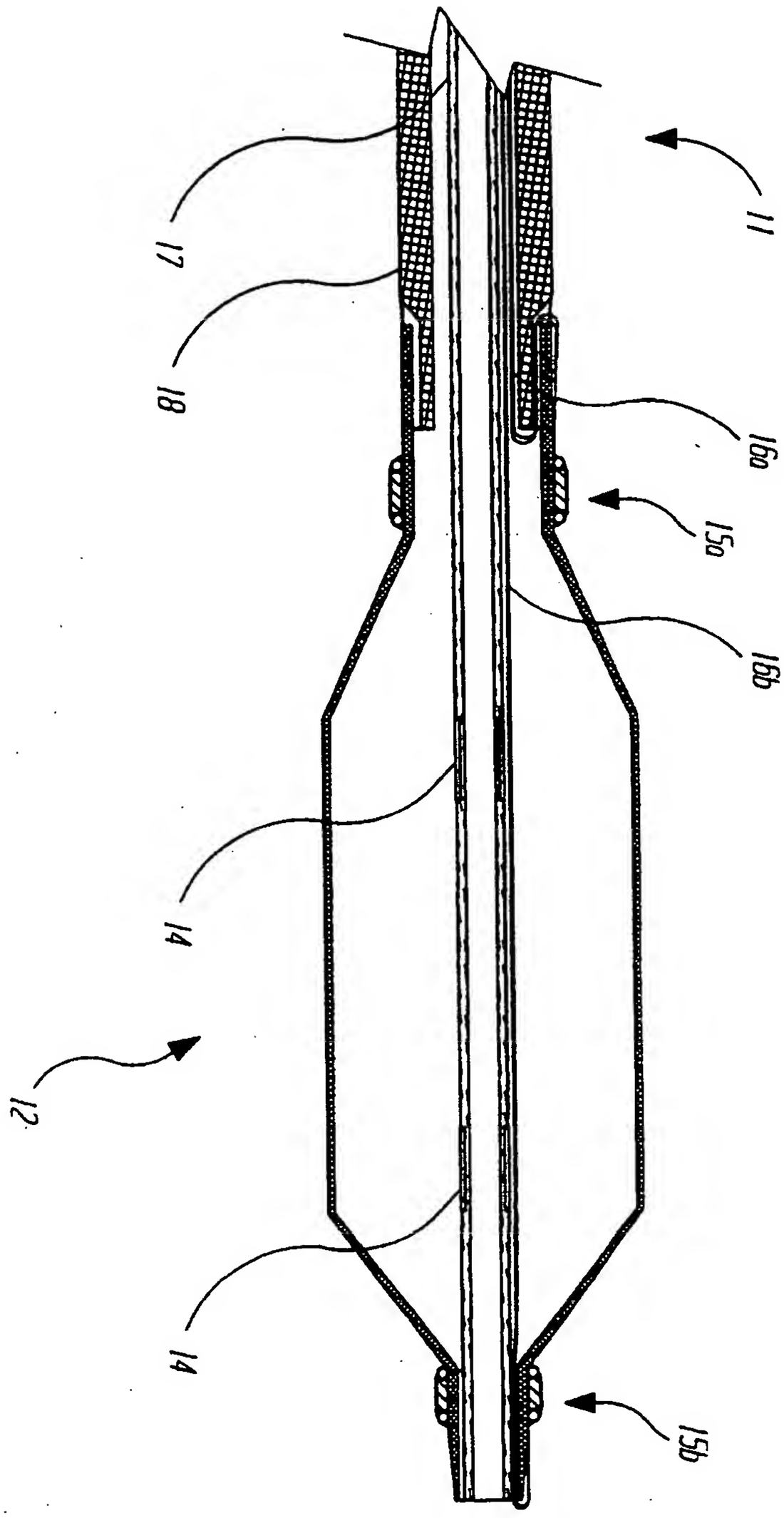


FIGURE 1b

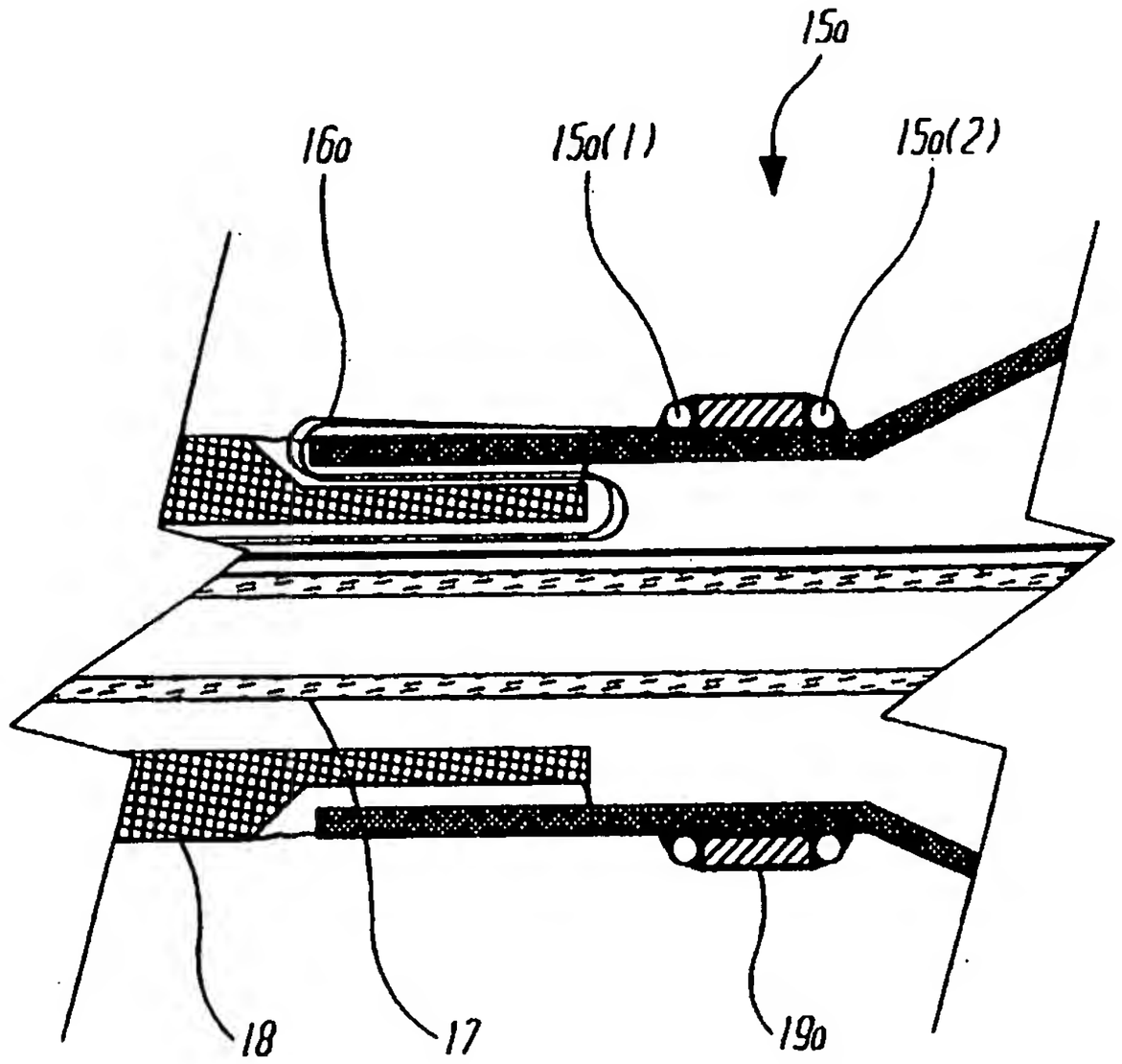


FIGURE 1c

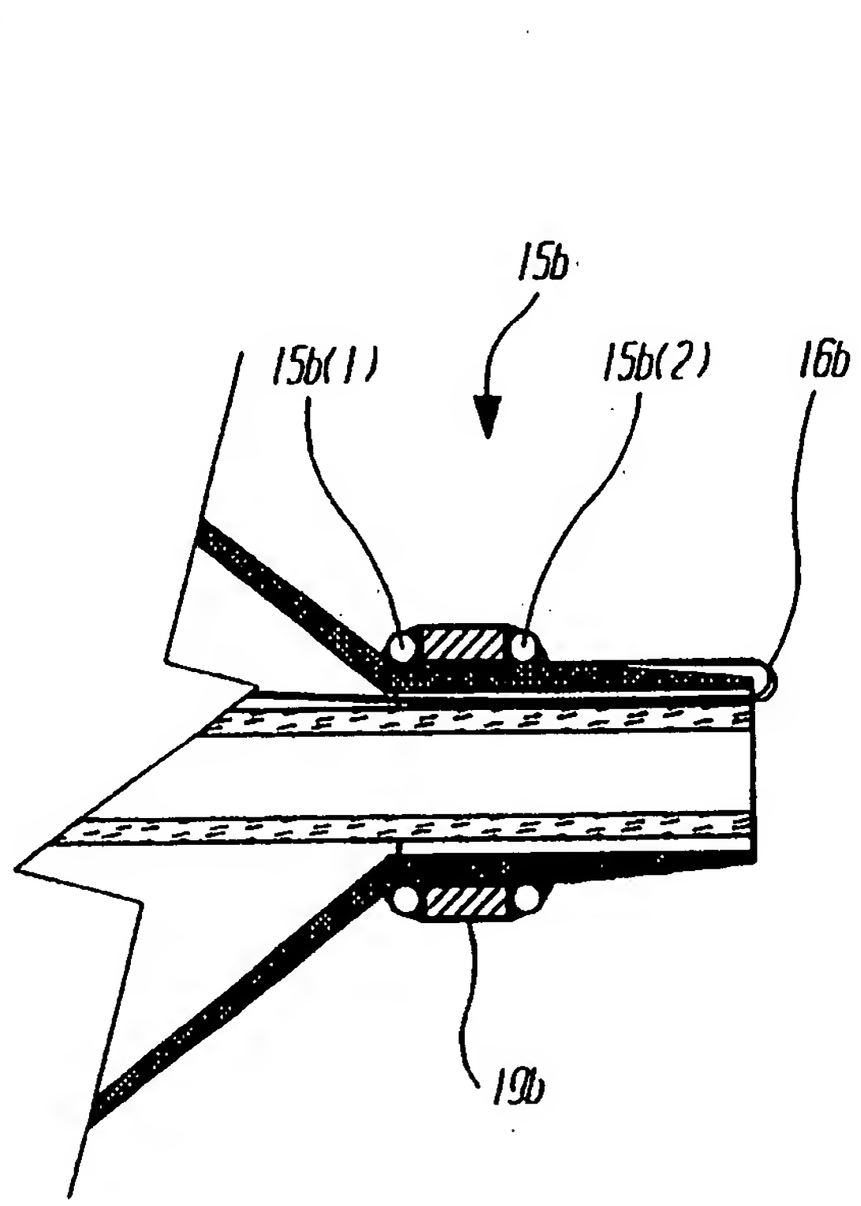


FIGURE 1d

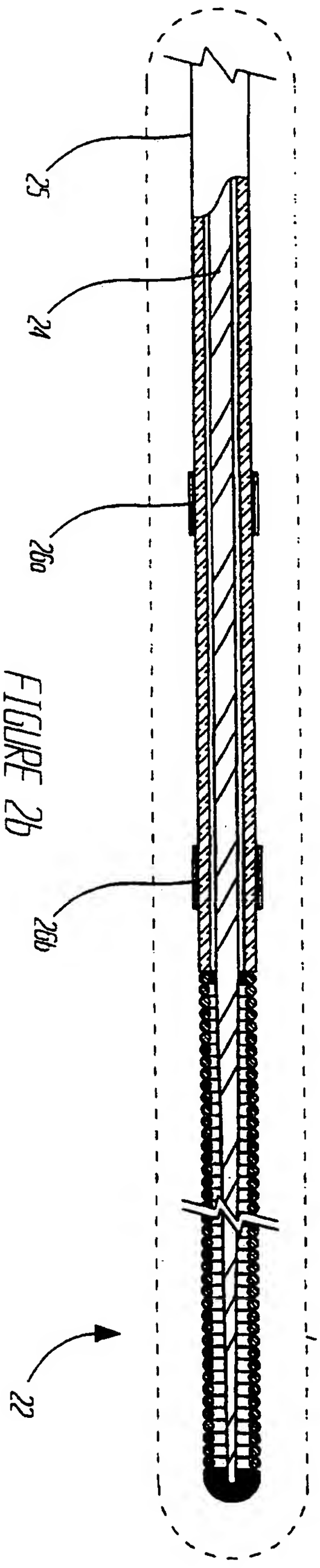


FIGURE 2b

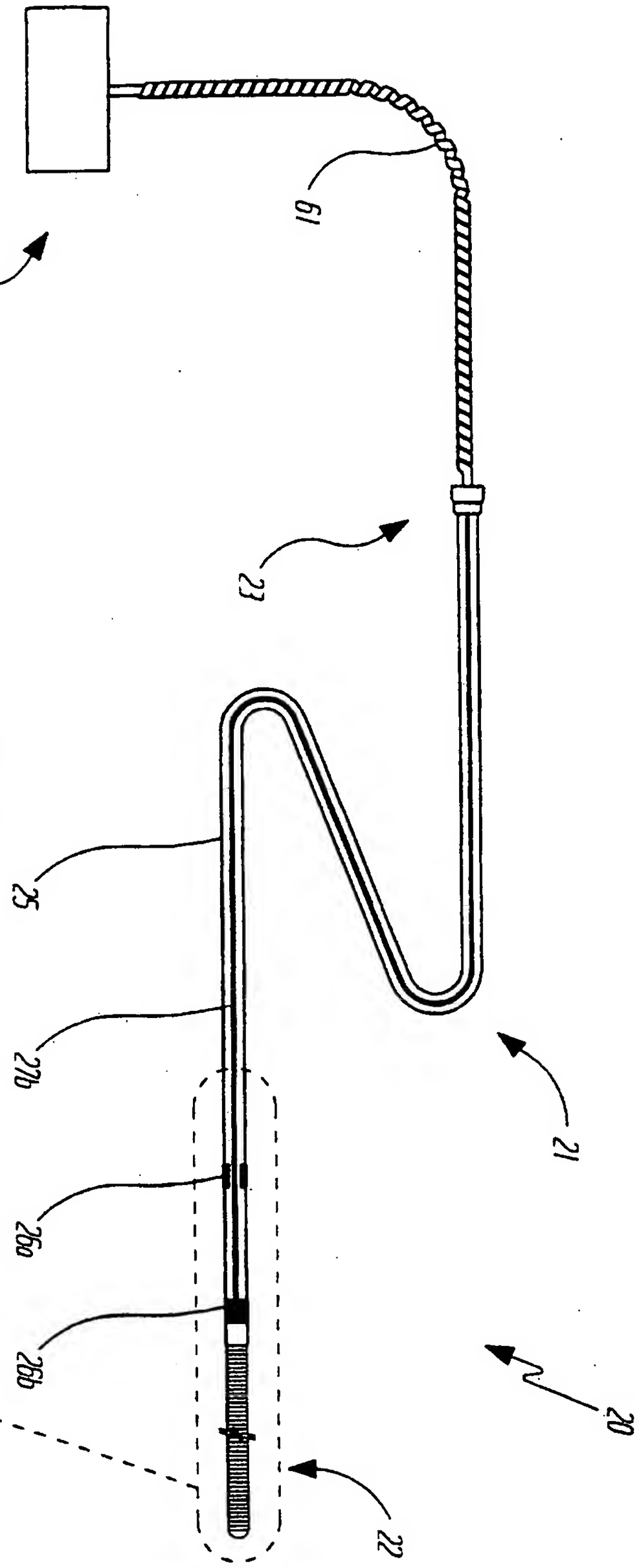


FIGURE 2a

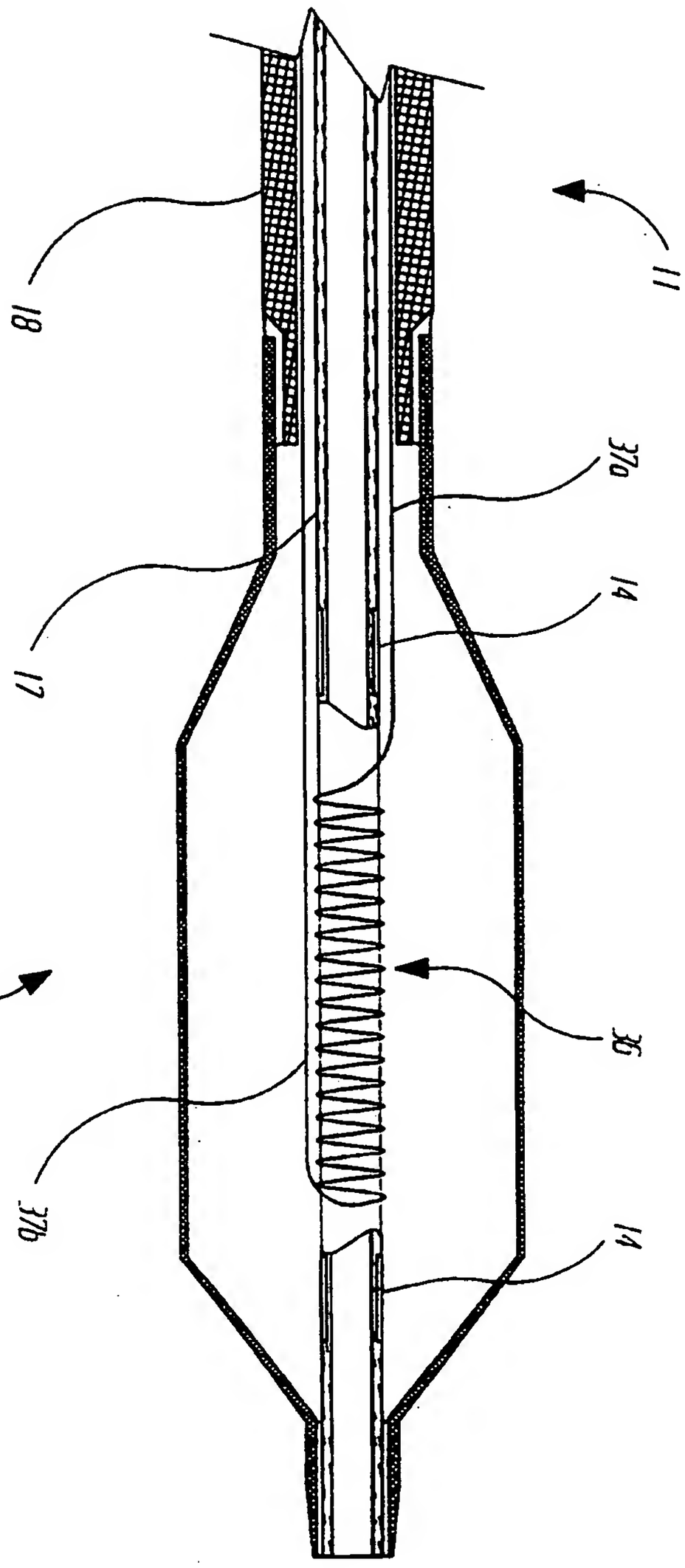


FIGURE 3

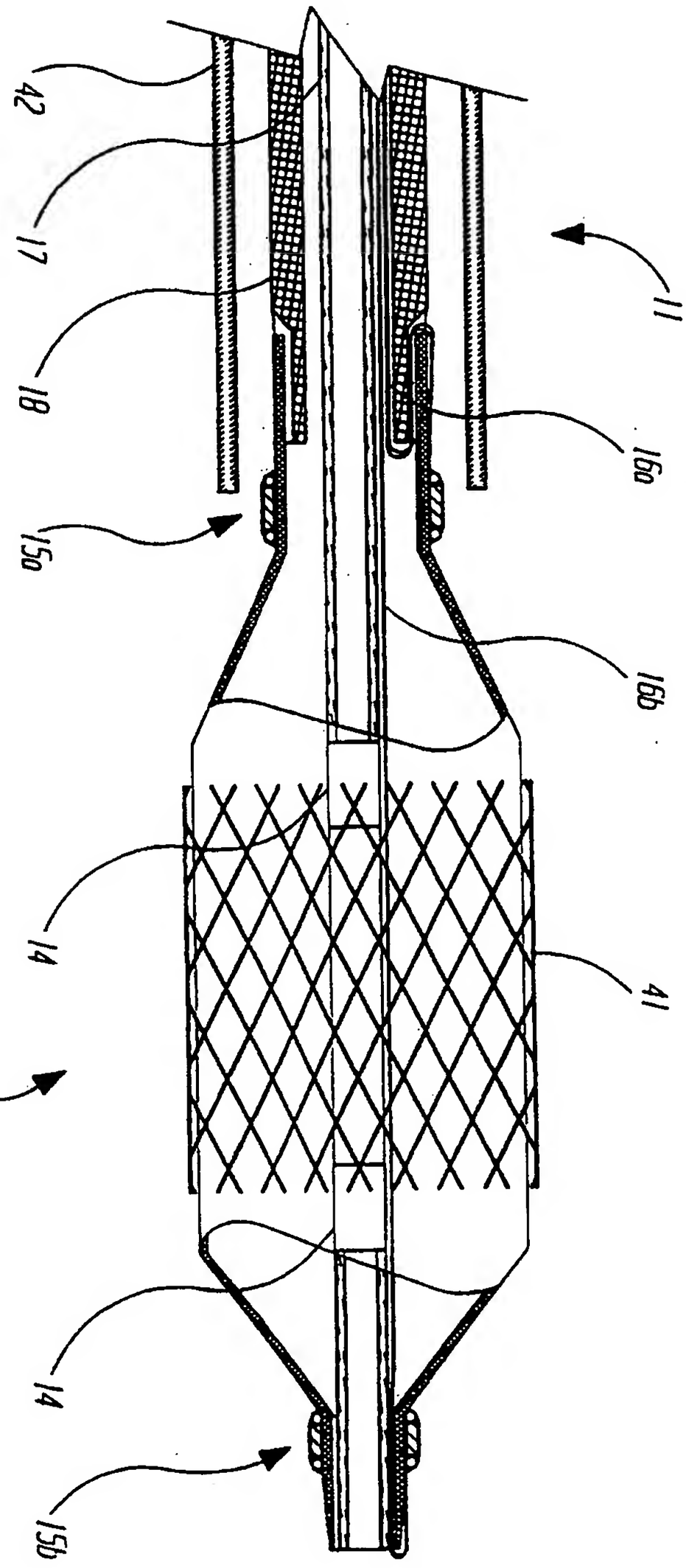


FIGURE 4

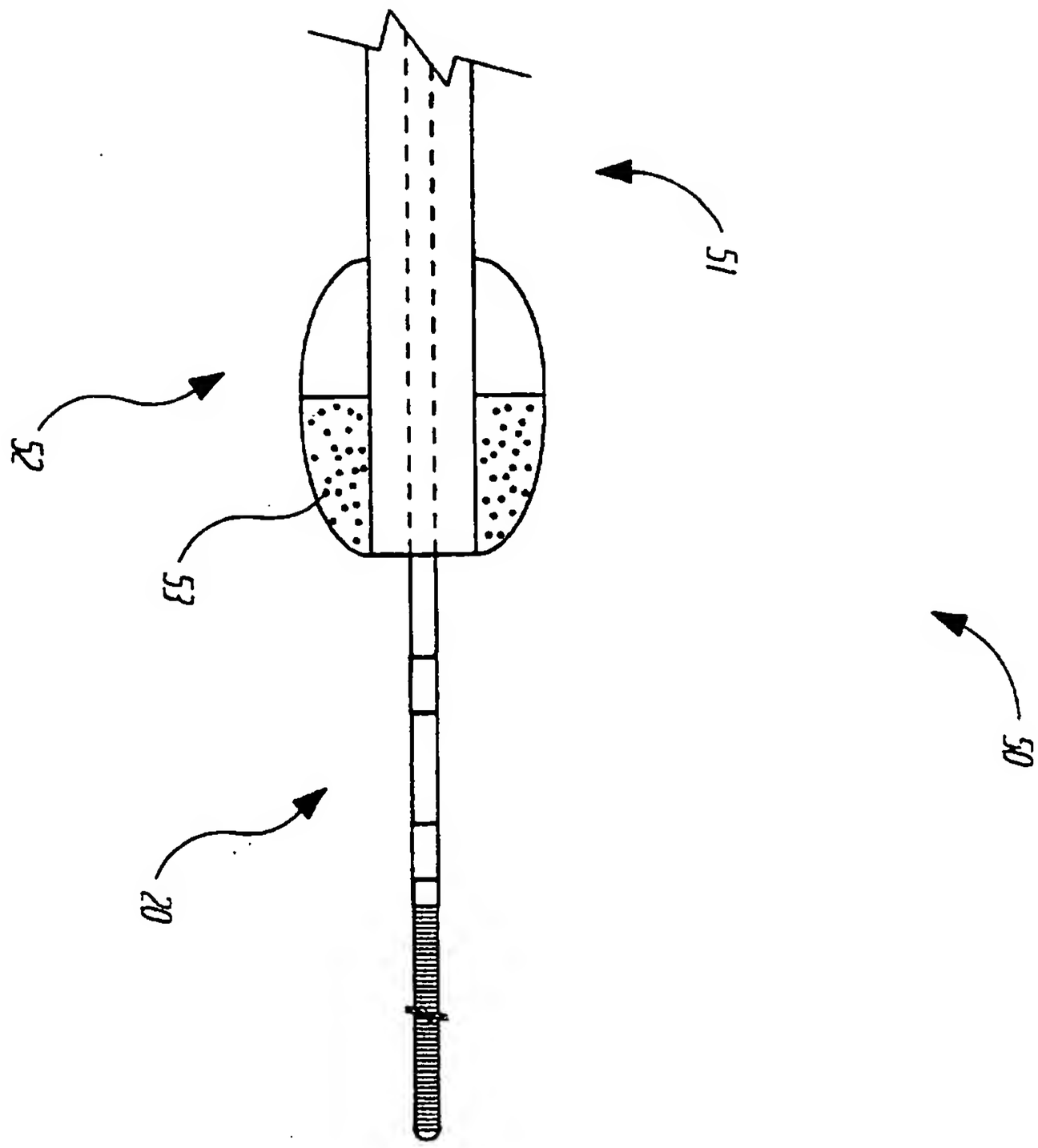


FIGURE 5

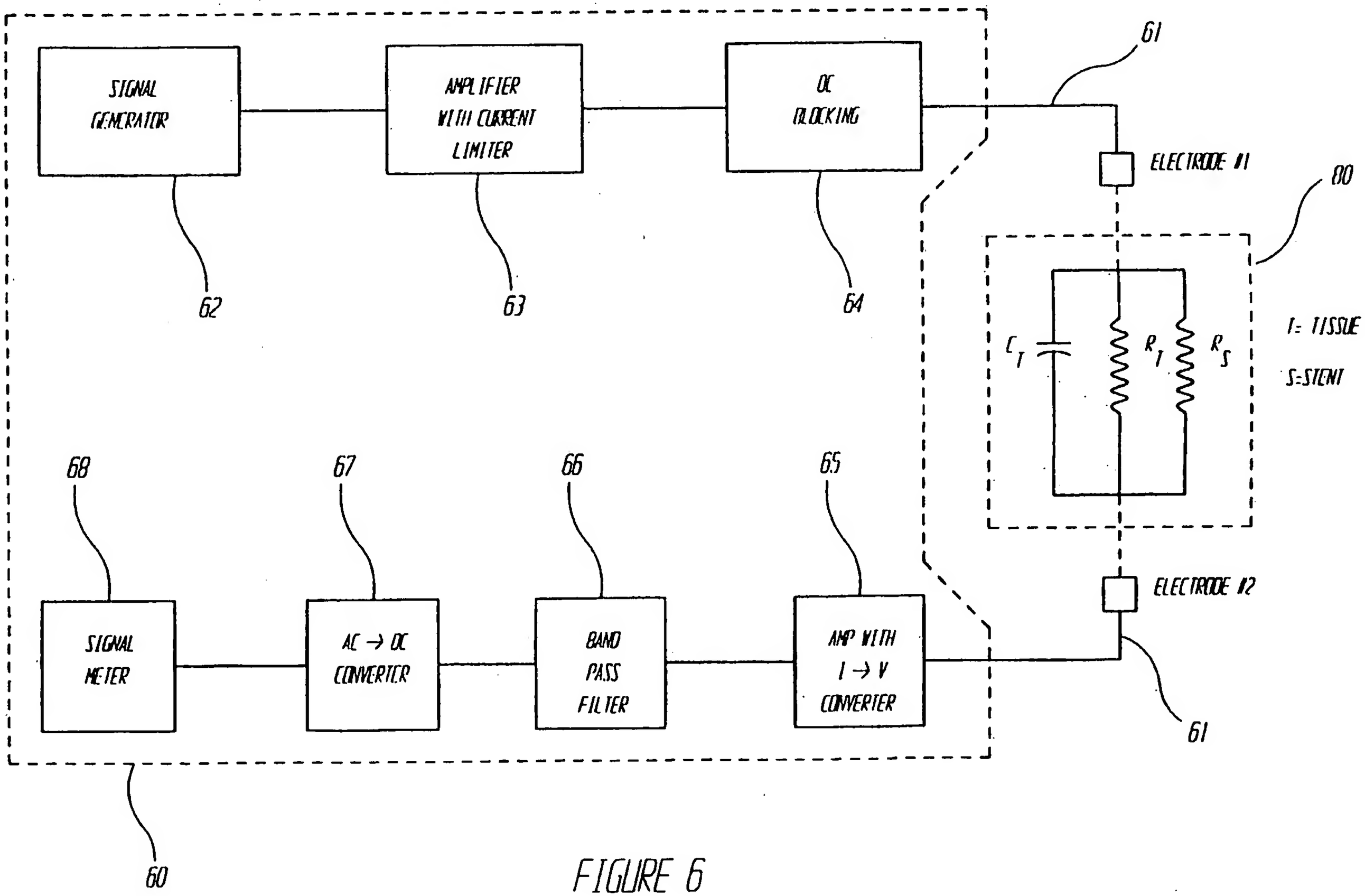
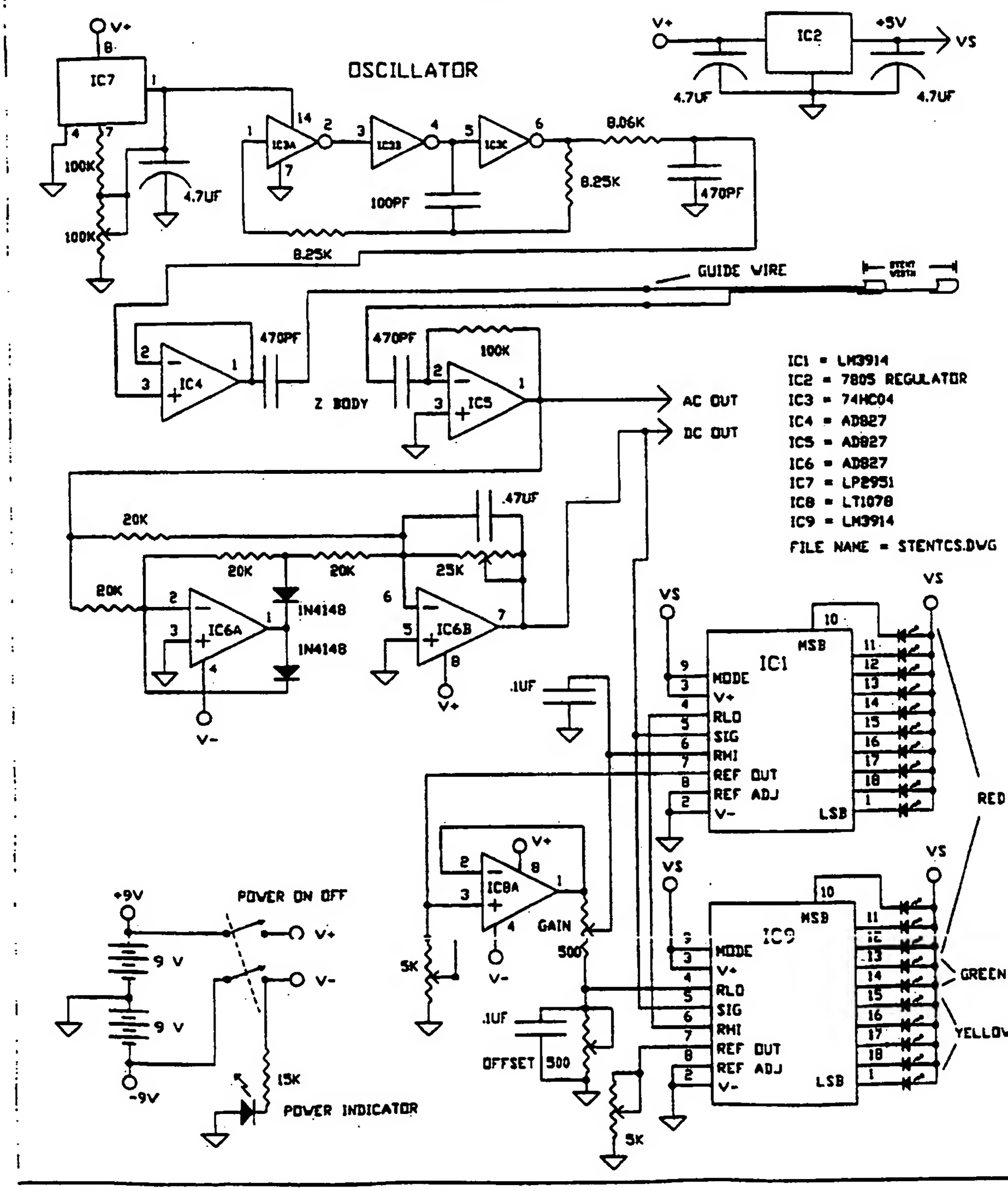

SIGNAL GENERATOR
AMPLIFIER WITH CURRENT LIMITER
DC BLOCKING
61
ELECTRODE #1
80
62
63
64
C_T
R_T
R_S
T= TISSUE
S=STENT
68
67
66
65
SIGNAL METER
AC → DC CONVERTER
BAND PASS FILTER
AMP WITH I → V CONVERTER
ELECTRODE #2
61
60

FIGURE 6

Fig. 7a


OSCILLATOR
V+
IC7
100K
100K
4.7UF
IC3A
IC3B
IC3C
100PF
8.06K
8.25K
470PF
8.25K
V+
IC2
+5V
VS
4.7UF
4.7UF
GUIDE WIRE
STENT WIDTH
IC4
IC5
470PF
470PF
100K
Z BODY
AC OUT
DC OUT
IC1 = LM3914
IC2 = 7805 REGULATOR
IC3 = 74HC04
IC4 = AD827
IC5 = AD827
IC6 = AD827
IC7 = LP2951
IC8 = LT1078
IC9 = LM3914
FILE NAME = STENTCS.DWG
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20K
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IC6B
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V-
V+
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VS
IC1
MSB
LSB
MODE
V+
RLO
SIG
RHI
REF OUT
REF ADJ
V-
RED
IC8A
GAIN
500
5K
OFFSET
500
.1UF
5K
VS
IC9
GREEN
YELLOW
+9V
POWER ON OFF
9 V
9 V
-9V
V+
V-
15K
POWER INDICATOR

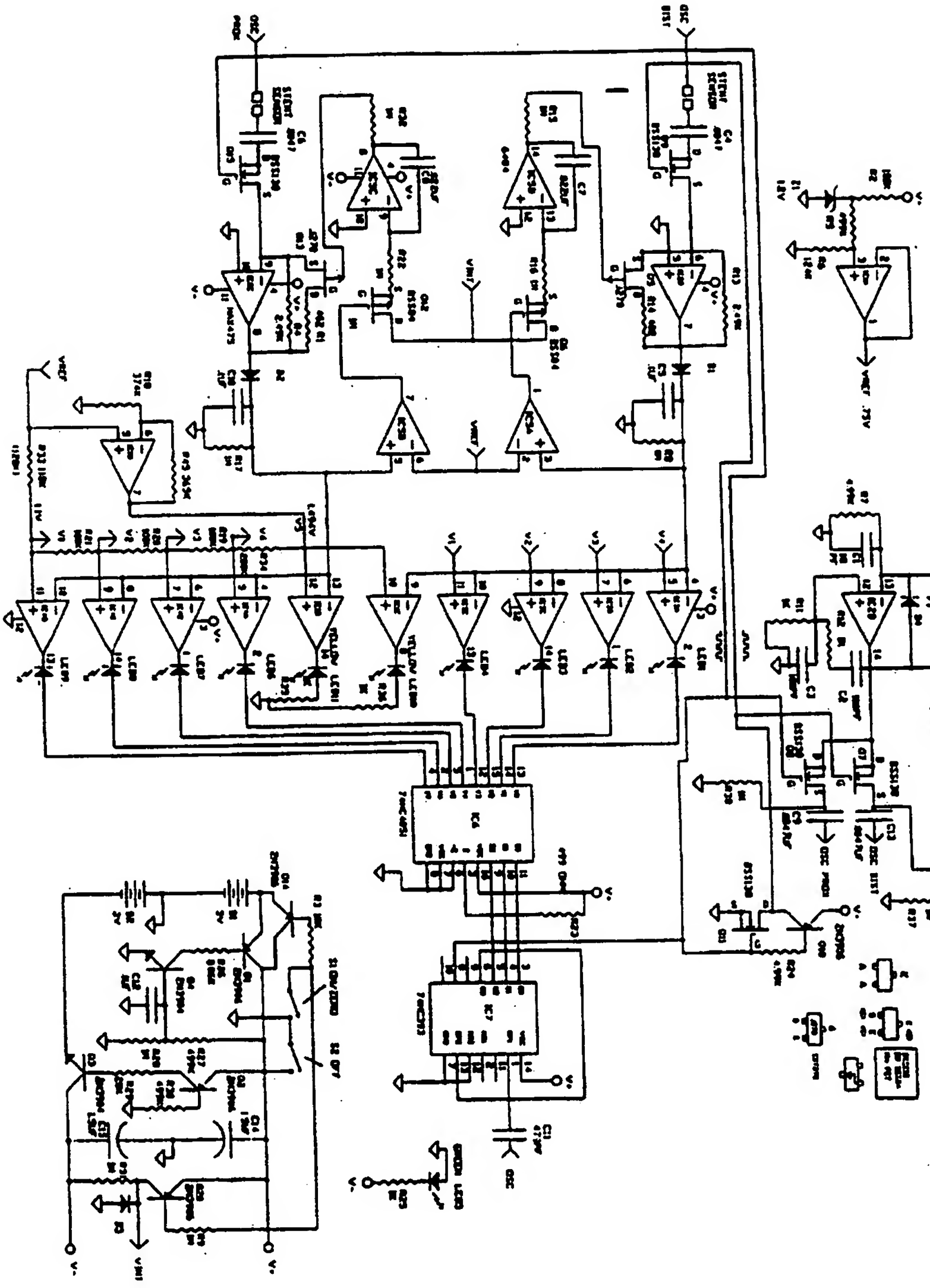

FIG. 7b

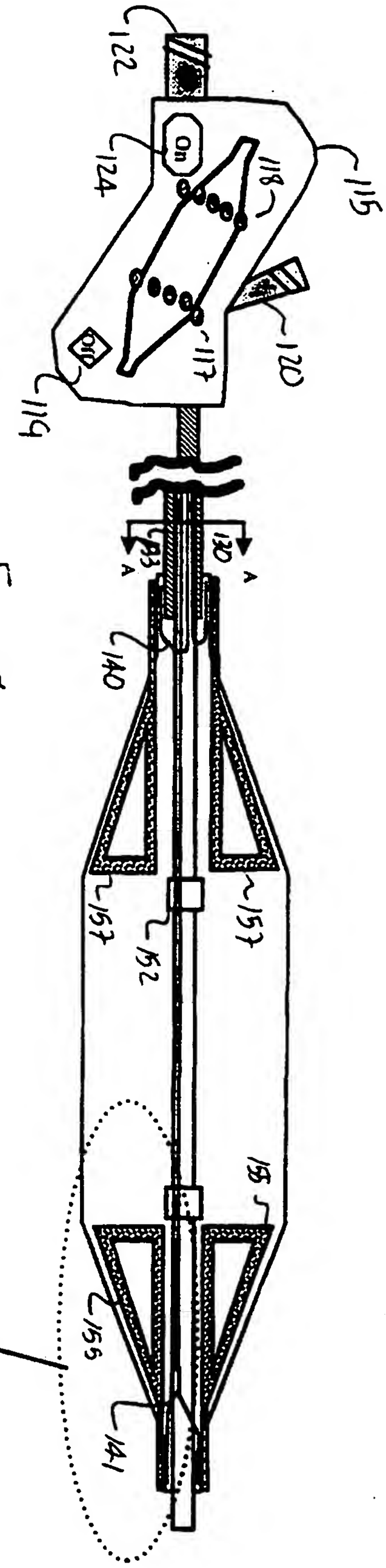
122
On
124
118
115
120
117
Off
119
130
A
123
A
140
157
152
157
155
156
141

FIG. 8

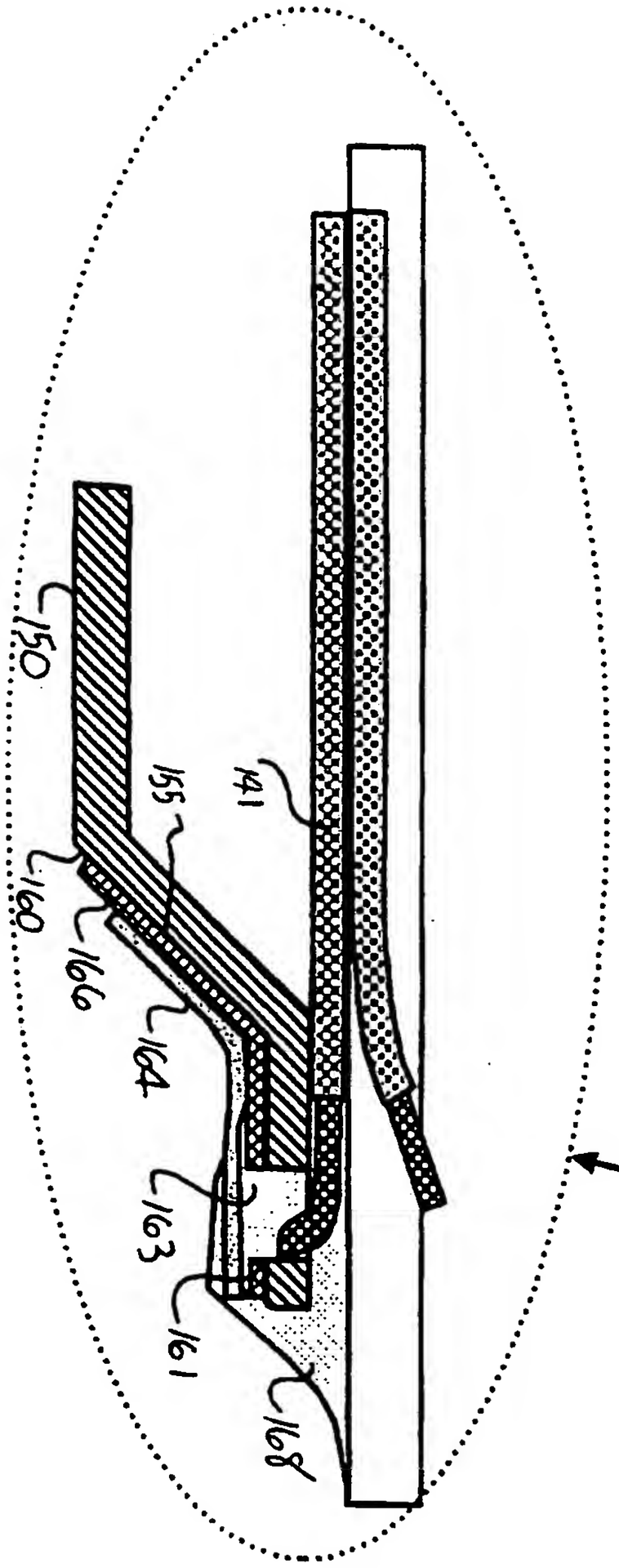
150
155
141
160
166
164
163
161
168

FIG. 12

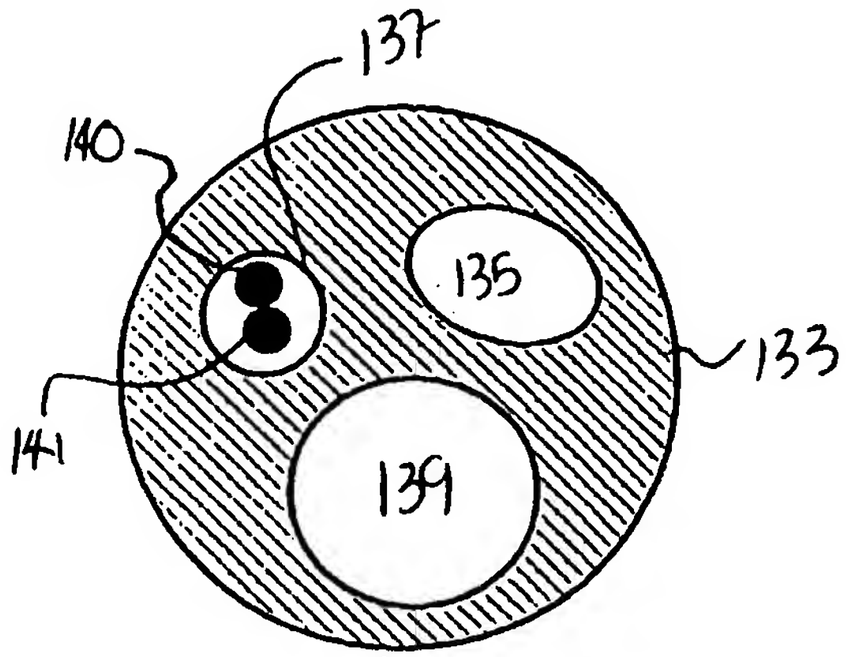

FIG. 9

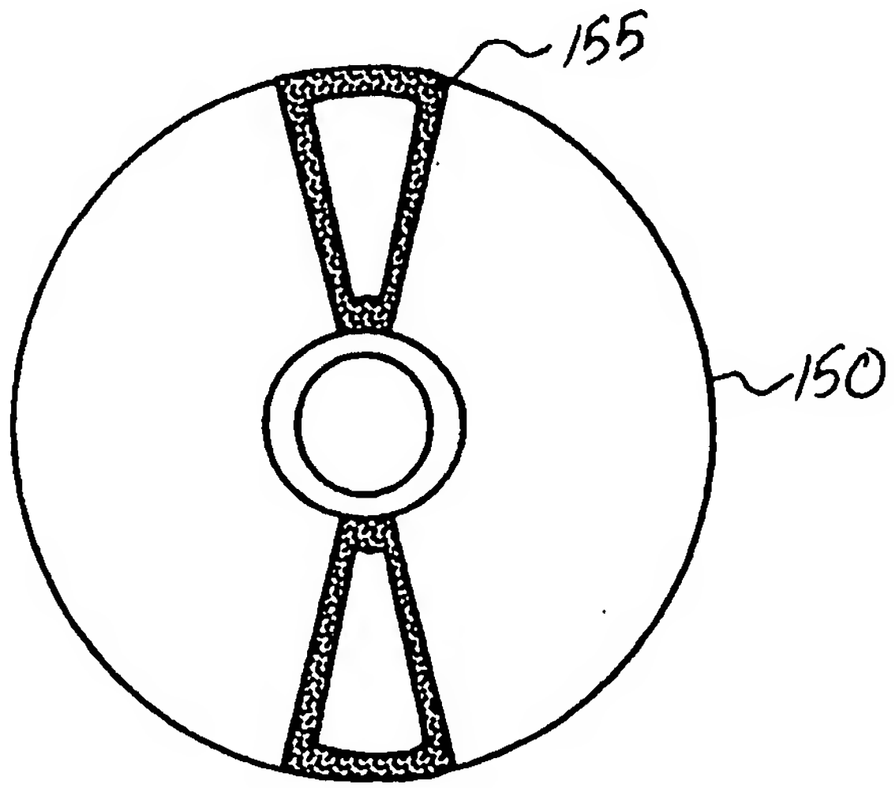

FIG. 11

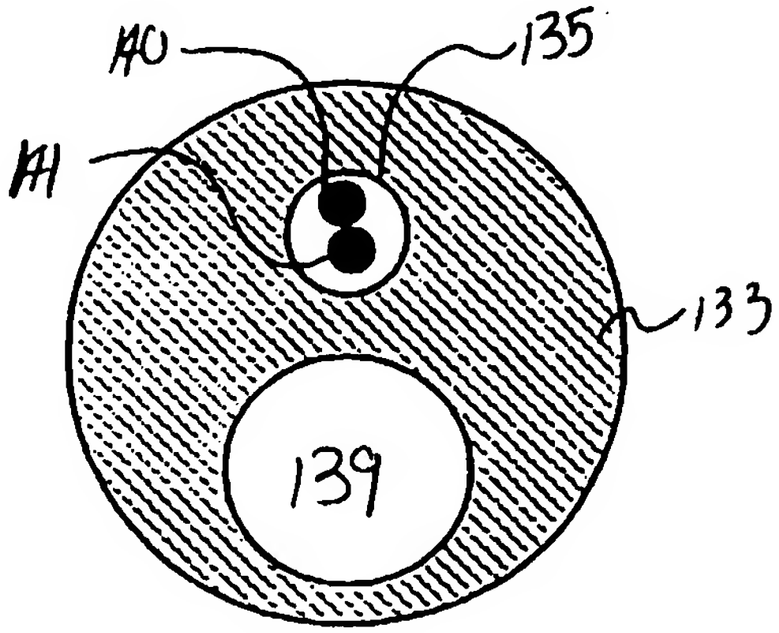

FIG. 10

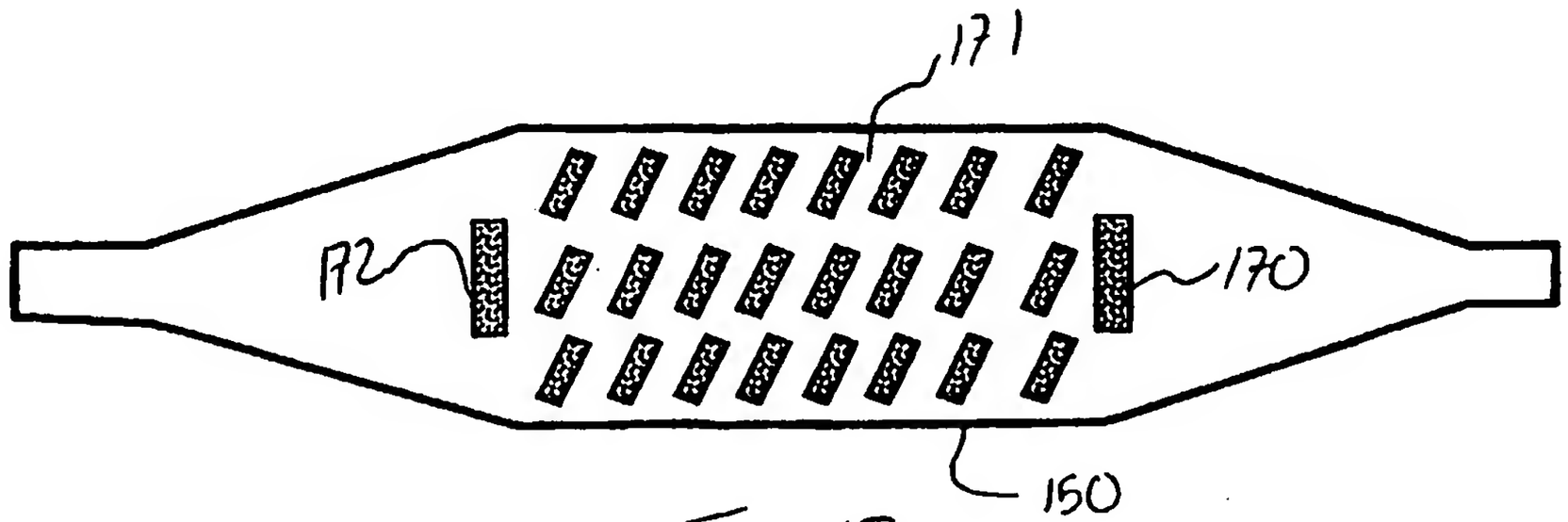

FIG. 13

INTERNATIONAL SEARCH REPORT

Inten ..nal Application No
PCT/US 97/03493

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/06 A61B5/05

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 94 24931 A (ARROW INTWRNATIONAL INVESTMENT) 10 November 1994 see page 4, line 12 - line 24; figure 1A ---	1-4
X	EP 0 498 303 A (YISSUM RESEARCH & DEVELOPMENT) 12 August 1992 see page 3, line 25 - line 37; figure 5 ---	1
A	WO 93 20770 A (CARDIORYTHM) 28 October 1993 see abstract; figures ---	1,6
A	WO 96 00528 A (EP TECHNOLOGIES) 11 January 1996 see abstract; figures ---	1,6
A	US 5 411 551 A (WINSTON ET AL.) 2 May 1995 --- -/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
18 July 1997	25.07.97

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax (+ 31-70) 340-3016	Hagberg, A

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Inten nal Application No
PCT/US 97/03493

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 647 435 A (ARROW INTERNATIONAL) 12 April 1995 ---	
A	WO 95 23558 A (TARGET TERAPEUTICS) 8 September 1995 -----	

2

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

national application No.
PCT/US 97/03493

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 12-51
because they relate to subject matter not required to be searched by this Authority, namely:
See Rule 39.1(iv) PCT.

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Intern. .onal Application No
PCT/US 97/03493

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